DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 30, 2015

ABB Optical Group, LLC
c/o Mr. Kevin M. Randall
Principal Consultant
Compliance Acuity, Inc.
P.O. Box 1490
Golden, CO 80402

Re: K142820
Trade/Device Name: BIOLENS (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: March 12, 2015
Received: March 16, 2015

Dear Mr. Randall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142820

Device Name
BIOLENS (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear

Indications for Use *(Describe)*
The BIOLENS Sphere (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is indicated for the correction of myopia and hyperopia in aphakic or non-aphakic patients with non-diseased eyes who exhibit no more than 2.00 D of astigmatism and can obtain satisfactory visual acuity in a power range of +20.00 to -20.00 D.
The BIOLENS Toric (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is indicated for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic or non-aphakic persons with non diseased eyes in a spherical power range of +20.00 to -20.00 D and a cylinder power range up to -10.0D.

The BIOLENS Multifocal (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is indicated for the correction of presbyopia in myopic and hyperopic eyes in aphakic or non-aphakic patients with non-diseased eyes who exhibit no more than 2.00 D of astigmatism and can obtain satisfactory visual acuity in a power range of +20.00 to -20.00 D and have near add requirements up to 3.25 D.
The BIOLENS Toric Multifocal (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is indicated for the correction of presbyopia in myopic, hyperopic and astigmatic aphakic or non-aphakic patients with non-diseased eyes in a spherical power range of +20.00 to -20.00 D, a cylinder power range up to -4.00 D and an add requirement up to +3.25 D.

BIOLENS lenses may be disinfected using chemical (not heat) disinfecting systems.

BIOLENS UV lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. Submitter Information

510(k) Owner: ABB Optical Group, LLC
1750 N. Loop Road, Ste. #150
Alameda, CA 94502 USA

Contact Person: Mr. Jeff Rinkus, COO
510-483-9400 (office)

Consultant & Submission Correspondent: Kevin Randall, Principal Consultant
ComplianceAcuity, Inc.
Golden, CO 80402
(303) 828-0844 (direct)
(303) 828-0835 (fax)
Email: info@complianceacuity.com

Date Summary Prepared: November 6 , 2014

II. Name of Device

Trade Name: BIOLENS (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear

Common/Usual Name: Soft (hydrophilic) contact lens

Classification Name: Lenses, Soft Contact, Daily Wear

Classification Regulation: 21 CFR 886.5925

USAN (generic name): Mangofilcon A

ABB OPTICAL GROUP

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

III. Device Description & Technological Characteristics

The BIOLENS (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is available in spherical, toric, multifocal, and toric-multifocal designs. Specifically, the BIOLENS models are hemispheric flexible shells of the following parameters:

	BIOLENS Sphere	**BIOLENS Multifocal**	**BIOLENS Toric**	**BIOLENS Toric Multifocal**
Diameter(s)	12.0 mm to 16.0 mm			
Center Thickness (Low Minus Lens)	0.07 mm dry			
Center Thickness (Plus Lens)	Up to 0.50 mm			
Base Curve(s)	8.0 mm - 9.5 mm			
Powers	-20.00 D to +20.00 D			
Cylinder Powers	Not Applicable (N/A)		Up to-10.00 D in steps of 0.25 D	Up to-4.00 D in steps of 0.25 D
Axis	Not Applicable (N/A)		1º to 180º	
Add Powers	N/A	+0.50D to +3.25D	N/A	+0.50D to +3.25D

All BIOLENS lenses are plasma treated in the dry state prior to initial hydration.

The lens material (mangofilcon A) is a non-ionic hydrophilic copolymer that consists of 51% mangofilcon A and 49% water by weight. Mangofilcon A is available clear (no tint) with or without a UV absorber to block a significant amount of the UV radiation occurring between 200 and 400 nm (UVA and UVB). Mangofilcon A is also available in Blue or Aqua visibility tints to assist with handling. Both colors are available with or without the UV absorber.

The physicochemical properties of BIOLENS (mangofilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear are tabulated at the top of the next page:

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

BIOLENS (mangofilcon A) Physicochemical Properties

Characteristic	Value
Dk	49 (Fatt Units @ 35ºC)
REFRACTIVE INDEX	Dry: 1.470
	Hydrated: 1.413
SPECIFIC GRAVITY	Dry: 1.112
	Hydrated: 1.109
LINEAR EXPANSION RATIO	1.26
WATER CONTENT	49%
LIGHT TRANSMITTANCE	Clear: 96%T
	Tinted: >70%T
PLASMA TREATMENT REQUIRED	Yes
SHORE D HARDNESS (blank form)	≥ 83

IV. Indications for Use

The **BIOLENS Sphere (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear** is indicated for the correction of myopia and hyperopia in aphakic or non-aphakic patients with non-diseased eyes who exhibit no more than 2.00 D of astigmatism and can obtain satisfactory visual acuity in a power range of +20.00 to -20.00 D.

The **BIOLENS Toric (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear** is indicated for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic or non-aphakic persons with non diseased eyes in a spherical power range of +20.00 to -20.00 D and a cylinder power range up to -10.0D.

The **BIOLENS Multifocal (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear** is indicated for the correction of presbyopia in myopic and hyperopic eyes in aphakic or non-aphakic patients with non-diseased eyes who exhibit no more than 2.00 D of astigmatism and can obtain satisfactory visual acuity in a power range of +20.00 to -20.00 D and have near add requirements up to 3.25 D.

The **BIOLENS Toric Multifocal (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear** is indicated for the correction of presbyopia in myopic, hyperopic and astigmatic aphakic or non-aphakic patients with non-diseased eyes in a spherical power range of +20.00 to -20.00 D, a cylinder power range up to -4.00 D and an add requirement up to +3.25 D.

BIOLENS lenses may be disinfected using chemical (not heat) disinfecting systems.

BIOLENS UV lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

V. Comparison to Legally Marketed Predicates

PROPERTY	BIOLENS (mangofilcon A) (subject device)	LSH (mangofilcon A) (1º predicate)	iO_2 (mangofilcon A) (2º predicate)
Marketing Status	Not Yet Cleared	K120756	K133079
USAN	Mangofilcon A	Mangofilcon A	Mangofilcon A
Device Class	II	II	II
FDA Product Code	LPL	LPL	LPL
Regulation	21 CFR 886.5925	21 CFR 886.5925	21 CFR 886.5925
Indications for Use	See section IV of this 510(k) Summary	Same* as subject BIOLENS	Same* as subject BIOLENS
Manufacturing Method	Lathe-cut	Lathe-cut	Lathe-cut
Plasma Treatment?	Yes	Yes	Yes
Water Content	49%	49%	49%
Oxygen Transmissibility	49 (ISO/Fatt)	49 (ISO/Fatt)	49 (ISO/Fatt)
Refractive Index	Dry: 1.470	Dry: 1.470	Dry: 1.470
	Hydrated: 1.413	Hydrated: 1.413	Hydrated: 1.413
Specific Gravity	Dry: 1.112	Dry: 1.112	Dry: 1.112
	Hydrated: 1.109	Hydrated: 1.109	Hydrated: 1.109
Shore D Hardness	≥ 83	≥ 83	≥ 83
Tensile Strength	3.07 M Pa	3.07 M Pa	3.07 M Pa
Elongation at Break	470%	470%	470%
Light Transmittance	Clear: 96%T	Clear: 96%T	Clear: 96%T
	Tinted: >70%T	Tinted: >70%T	Tinted: >70%T

* Although UV protection is emphasized in the BIOLENS indications per Agency request, the UV protection offered by the BIOLENS is the same as the predicates.

VI. Summary of Non-Clinical Performance Data

A combination of relevant non-clinical analysis and testing has been assured, including:

• Chemical composition of finished lenses	• Color and light transmittance
• Purity of initial monomers	• Refractive index
• Shelf Life	• Water content
• Leachability of Residual Monomers	• Oxygen transmissibility
• Leachability of Color Additives / UV Absorber	• Specific gravity
• Biocompatibility testing	• Mechanical Testing & Hardness
• Preservative Uptake and Release	• Lens/Solution Compatibility

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

VIII. Conclusions Drawn

It is the conviction of ABB Optical Group that the information and data submitted in this premarket notification substantiate our ability to manufacture a contact lens with a safety and effectiveness profile that is substantially equivalent to the predicate devices, and that *does not raise* different questions of safety and effectiveness. Based on these facts, ABB Optical Group therefore concludes that the subject device is as safe and as effective, that is, "substantially equivalent" to, the predicates pursuant to section 513(i) of the Act.

END OF 510(k) SUMMARY